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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,371	10/19/2001	Alexander K. Khairkahan	MVMDINC.001CP2	7973

20995 7590 11/14/2003

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EXAMINER

DAWSON, GLENN K

ART UNIT PAPER NUMBER

3761

DATE MAILED: 11/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,371

Applicant(s)

KHAIRKHAHAN ET AL.

Examiner

Glenn K Dawson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-27 and 32-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 60-71 is/are allowed.
- 6) ☒ Claim(s) 18-25, 27, 32-47, 49-55, 58 and 59 is/are rejected.
- 7) ☒ Claim(s) 26, 48, 56, 57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 44,45 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Tassel, et al.-6551303 B1.

Van Tassel discloses a method of implanting a device into the LAA by providing an implantable device 160,40, placing the device into the LAA in the collapsed configuration and then expanding the device by moving the proximal end closer to the distal end. See fig. 20-22. Col. 9 lines 22-43 disclose that the device can be self-expandable as well as manually actuatable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19,34-36,49 and 51 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Van Tassel, et al.-WO 01/30266 A1.

Van Tassel discloses a method of implanting a device into a LAA comprising positioning a device into the LAA and manipulating a control to enlarge the device under positive force. See fig. 44,45 and 98-100 and accompanying description. Tissue anchors abut the wall of the LAA and lock the device in place. Embodiments have spokes, and use torqueable threaded rods or cores to move proximal and distal ends of

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the devices together and apart to shorten and enlarge, and lengthen and retract the devices for introduction and deployment of the devices into the LAA. In fig. 45, element 491 can be either the claimed core or pull wire. However, it is not specifically disclosed that these embodiments use a deployment catheter, or that the device is maintained in its collapsed configuration by maintaining the core against a distal surface while using the deployment line to hold still the proximal end of the device.

As most of the other embodiments are introduced into the patient's body by use of a deployment catheter, the examiner considers it inherent that a deployment catheter would be used to introduce the device into the LAA, however, lacking a finding of inherency, to have used a deployment catheter to introduce the disclosed devices as shown in the above noted figures would have been obvious as catheters are usually used to gain access to this part of the body. To have used the device as shown in fig. 45 in a collapsed condition by pushing forward on core 491 attached to the distal end of spokes 478 while holding the proximal end of the device still by holding the deployment line 489 still once placed in a reduced configuration for introduction into the LAA is again considered to be inherent given the figure as shown. However, absent this finding, it clearly would have been obvious to have kept the device in a reduced diameter configuration in such a manner as one skilled in the art would recognize that opposing forces on the core and deployment line are needed to cause retraction of the device and that maintaining this position is necessary to hold it in this reduced configuration.

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Claims 18,20-25,27,32-35,37-43,46,47,53-55 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel, et al.-6551303 in view of Van Tassel-'266

Van Tassel discloses a method illustrated in fig. 20-22 whereby a device with spokes 160 is introduced into a LAA 13 and expanded by use of a positive force or by self-expansion. See col. 9 lines 21-43. However, the use of a deployment catheter is not disclosed.

Van Tassel-'266 discloses LAA filter devices placed in position by use of deployment catheters 125,410,442,450,... etc. It would have been obvious to have used a deployment catheter to introduce the device shown in fig. 20-22 into position, as catheters are commonly used to gain access to this location of the body as evidenced by Van Tassel.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel-'266.

Van Tassel discloses the invention as claimed with the exception of the moving of the core in the proximal direction relative to the deployment line to enlarge the device. Noting fig. 45, one skilled in the mechanical arts would readily recognize that either moving the core 491 proximally or moving the deployment line distally or both is required to actuate the device to cause it to enlarge. Any or a combination of these 3 motions would be considered obvious by which to actuate the device.

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Allowable Subject Matter

Claims 26,48,56 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 60-71 are allowed.

Response to Arguments


Applicant's arguments with respect to the rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Glenn K Dawson
Primary Examiner
Art Unit 3761

Gkd
07 November 2003